

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

LOREM VASCULAR, Pte. Ltd., a Singapore Company,)	
)	
Plaintiff,)	C.A. No. 21-885-MN
)	
v.)	
)	
PLUS THERAPEUTICS, INC., f/k/a CYTORI THERAPEUTICS, INC., a Delaware Corporation; and DOES 1 through 30, inclusive,)	
)	
Defendants.)	

**DEFENDANT’S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS
PLAINTIFF’S COMPLAINT**

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I. INTRODUCTION

Lorem’s case hinges on a false premise: that it allegedly bargained for and should have received valid CE certifications for the medical devices assembled at the Cytori UK facility as part of the parties’ Asset and Equity Purchase Agreement (“APA”). But the APA, which is incorporated by reference into the Complaint, undeniably did not include CE certificates for that UK facility in its list of transferred Permits—it only included a *different* CE certificate that Lorem does not dispute was valid when transferred. Plus went even further in the APA, disclosing that the UK facility was “not in compliance,” was behind on its audits, and could not export to the UK or EU. Plus cannot be faulted for failing to deliver a CE-certified UK facility when it never made that promise to begin with. Because Lorem cannot plausibly allege that Plus misrepresented the status of its CE certificates, all of its claims should be dismissed.

Lorem’s attempt to cast a March 2019 shipment of product to China without a valid CE certification as a separate source of breach also fails. As Lorem concedes, its Complaint is silent on how that shipment supposedly violated any law. For the first time in its Opposition, it identifies a now-superseded Decree issued by the People’s Republic of China in 2014, citing to an unverified and unreliable machine translation website. That Decree—including the effective 2017 version from a reputable source—far from establishes any violation of law.

Lorem’s claims, all of which sound in fraud and are subject to Rule 9(b), should be dismissed because: (1) Lorem has not proffered a reasonable interpretation of any representation and warranty in the APA that Plus breached by not tendering valid CE certificates for the UK facility or by shipping product to China in March 2019; (2) Lorem has not identified any implied obligations in the APA that Plus breached; (3) Lorem’s fraud claim is a disguised breach of contract claim, and in any event does not allege any false statements or reasonable reliance; and (4) Lorem does not allege any fiduciary or special duty giving rise to a negligent misrepresentation

claim. The APA was negotiated years ago by sophisticated parties represented by counsel. The parties specifically discussed the CE certificates at issue, and Lorem was well aware that they were not part of the deal and the UK facility they were associated with was out of compliance. The Court should reject Lorem's attempt to rewrite the APA, and dismiss the Complaint.

II. ARGUMENT

A. Lorem Fails to Allege That Plus Breached the APA

Lorem does not dispute that, despite pleading numerous APA representations and warranties that were supposedly false, its breach of contract claim is entirely premised on the allegation that the CE certificates for products assembled at the Cytori UK facility were not valid. *See* D.I. 10 ("Mot.") at 6; D.I. 15 ("Opp.") at 2, 4-5. Nor does it dispute that the heightened pleading requirements of Rule 9(b) apply to its contract claims because they sound in fraud. *See* Mot. at 1-2, 5, 16. Lorem fails to allege—with particularity or under Rule 8—how Plus breached the APA by failing to tender a UK facility with valid CE certificates. *See* Compl. ¶¶ 4-6, 36, 43.

Lorem's Opposition confirms that its breach of contract claim is based on an implausible theory that directly contradicts the APA. *See* Opp. at 2, 4-5. According to Lorem, it believed at the time of the APA it was purchasing two CE certificates for Cytori's UK facility (Nos. 619294 and 622786) and that those certificates were valid. *See, e.g.,* Compl. ¶¶ 5, 18-19. However, ***Plus transferred neither of those certificates to Lorem under the APA.*** Neither CE certificate numbers 619294 nor 622786 are included in Disclosure Schedule 3.10(b) and Exhibit 3.10(b) to the APA, which identify and attach the CE certificates that Plus transferred.¹ *See* D.I. 11 ("RJN") Ex. 1.

¹ Lorem's Opposition attempts to rewrite the APA, arguing that Disclosure Schedule 3.10(b) includes "[t]he certificates included in Exhibit 3.10(b) to these schedules [i.e., the CE certificates for the Cytori UK Facility.]" Opp. at 4. The bracketed language does not appear in the APA, and Exhibit 3.10(b) does not include "CE certificates for the Cytori UK facility." APA Exhibit 3.10(b) attaches a single CE certificate associated with the US-based entity, Cytori Therapeutics, Inc. (No. 544833). RJN Ex. 1 at Ex. 3.10(b). There is no reasonable interpretation of the APA that supports that CE certificate Nos. 619294 and 622786 were included.

But because the parties did not attach CE certificate Nos. 619294 and 622786 in Exhibit 3.10(b), Lorem acquired no rights to those certificates and Plus made no representation or warranties as to their validity or force and effect in APA Section 3.10(b). As a result, when Plus disclosed in Disclosure Schedule 3.10(b) that the UK facility was “[n]ot in compliance,” had not performed a required audit, and could not export to the UK or EU, it was not making any representation about whether or how those un-transferred CE certificates could be restored. *See* RJN Ex. 1.

Lorem’s attempt to fall back on supposed ambiguity in the APA fails because no interpretation of the representations and warranties can change the fact that Lorem did not acquire any CE certificates for Cytori UK. *See* Opp. at 3-4; *see also Johansson v. Ferrari*, No. CV 14-42-GMS, 2015 WL 5000848, (D. Del. Aug. 20, 2015) (rejecting argument contradicted by document incorporated by reference into the complaint). As explained below, Lorem does not identify any reasonable interpretation of any provision in the APA that Plus breached.² *See* Opp. at 5-10.

Section 3.01: This is a standard representation regarding *corporate power and authority* to enter the APA and conduct business. *See* L. Kling and E. Nugent, *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* § 11.04 (17th ed. 2001) (Corporate power and authority representations do “not purport to pick up regulatory or similar authority . . . necessary to conduct the Company’s operations.”). Lorem does not allege Plus or Cytori UK lacked corporate power or authority to manufacture or sell products. It is not reasonable to interpret this provision to require a certification of compliance with technical requirements, testing, and certification procedures issued by a regulatory authority. *See* Compl. ¶¶ 13-14 (describing CE certification).

Section 3.06: It is not reasonable, as Lorem argues, to interpret the defined term “Books and

² Lorem cites *Anschutz Corp. v. Brown Robin Capital, LLC*, 2020 WL 3096744 (Del. Ch. Jun. 11, 2020) to support its interpretations of the APA. *See* Opp. at 5-7, 9-10. But in *Anschutz*, the defendants listed the at-issue agreement as a material contract in their disclosure schedule. *Id.* at *9. Here, the APA does not include a CE certificate for the UK facility. *See* Section II(A), *supra*.

Records” to include CE certificates and related paperwork, including a “cancellation letter.” *See* Opp. at 6. Lorem does not identify any item in the Books and Records definition that would encompass a CE certification, and it explicitly excludes “Clinical Files,” which is itself defined as “all clinical *and regulatory files*, filings, *correspondences* and reports (including submission information) *with any Governmental Authority...*” RJN Ex. 1 at § 1.01 (emphasis added). “Governmental Authority” includes “any . . . notified body,” such as BSI. *Id.*; *see also* Compl. Exs. A, C, D. Cytori’s regulatory files regarding issuance of CE certificates, and its correspondence with BSI about their suspension and cancellation, are Clinical Files excluded from the Books and Records. *See id.* There is no other reasonable interpretation of this provision.

Section 3.08: Lorem asserts that the March 2019 shipment to China was a “material damage, destruction or loss.” Opp. at 7. Lorem omits that the shipment could only violate Section 3.08 if it constituted “material damage, destruction or loss . . . *of any Purchased Asset.*” RJN Ex. 1 § 3.08 (emphasis added). Lorem fails to allege or explain how a \$67,200 shipment on March 26, 2019—for which Lorem was separately invoiced, *see* Compl. ¶ 19(iii), Ex. B—could be a “Purchased Asset” as defined in the APA. RJN Ex. 1 § 2.02, Disclosure Schedule 2.02. It is not.

Section 3.10(a): Lorem does not dispute that merely not having a valid CE certificate did not violate any law or governmental order. *See* Mot. at 11. The only violation Lorem alleges relates to a March 2019 shipment of product to China. Compl. ¶ 36(iv). Although the Complaint contains no allegations about why the shipment was purportedly illegal, Lorem argues in its Opposition that the shipment violated an unofficial machine translation of Chinese Decree No. 650. Opp. at 8 n.4; *see also* Kowalski Decl. Ex. 3.³ Aside from being an unreliable, unverified

³ Decree No. 650, which was issued in 2014, was superseded in 2017 by Decree No. 680. Kowalski Decl. Ex. 5. Lorem’s claims about the March 2019 shipment are based on an issue of foreign law, so it was required to provide notice of that law in its pleading. Fed. R. Civ. P. 44.1; *see also id.* at advisory comm. notes (1966). The Complaint certainly does not provide the requisite notice under Rule 9 (or Rule 8), nor does Lorem’s link to an unverified machine translation in its brief.

translation, Article 11 of that Decree (mis-cited as Article 9) does not establish illegality because (1) it explicitly applies only to Class II and III products, and Plus's products were registered in China as Class I devices, *see* Opp. at 8 n.4, Compl. ¶ 3, and (2) even for the devices it covers, it does not require any particular type of certification, such as CE certification.⁴ Kowalski Decl. Ex. 5. Lorem also has not alleged violation of Article 42, which merely requires the product attach Chinese instructions and labels that *indicate* country of origin, not that the products must comply with any particular standard in the country of origin. *Id.* Lorem also does not even attempt to cite any Chinese law supporting its allegation that a Free Sale Certificate was required for the shipment or that a Free Sale Certificate would be invalid if the CE certificate was revoked. *See* Compl. ¶ 16.

Section 3.10(b): Plus made no representations about the compliance of CE certificates that were not identified in Schedule 3.10(b). There can be no dispute that Schedule 3.10(b) did not identify CE certificate Nos. 619294 and 622786, and disclosed the UK facility's non-compliance.

Section 3.10(c): Lorem identifies no "submission" to any Governmental Authority that was not "true, complete and correct in all material respects as of the date of submission" or that any "required updates, changes, corrections or modifications" were not "submitted to" that Governmental Authority. *See* Opp. at 8. Indeed, Lorem attaches to the Complaint correspondence confirming that Plus updated its Notified Body, BSI, that its CE certificates would be canceled for failure to obtain a required audit. *See* Compl. Exs. C, D. Lorem cannot add to or modify this representation to inject a representation about the current validity and force of any CE certificate.

Section 3.10(d): The only set of facts or circumstances that Lorem alleges "would reasonably be expected to serve as the basis for" any Action for violation of law is the March 2019 shipment to China. *See* Opp. at 9. As explained above, Lorem has not alleged that shipment

⁴ Generally speaking, Class I are lower risk devices, Class II are medium risk devices, and Class III are higher risk devices. *See* Kowalski Decl. Ex. 5 at Art. 4.

violated any law, let alone that it would reasonably be expected to lead to legal action. Lorem concedes that shipment never prompted any regulatory or other legal action.⁵ *See* Mot. at 12-13.

Section 3.10(e): The only potential “grounds” for product recall that Lorem alleges is the March 2019 shipment to China. *Id.* As explained above, Lorem does not adequately allege anything improper with that shipment. It certainly does not allege a product defect or risk to health, which are the conditions that might lead to the recall of a product from the market.⁶

Section 3.15: This Section only applies to assets that were used to operate the Business as it was operated at the time of the APA, and as it had been conducted “in the past year.” CE certificate Nos. 619294 and 622786 were not assets used to operate the Business during that period because (1) they were suspended in January 2018, and (2) there is no allegation the products were on the market in the EU or UK after that. Lorem tries to rewrite this provision to refer to assets used to operate the business in “the year prior to the APA,” *i.e.*, all of 2018 and the three months of 2019 that preceded the signing of the APA. Lorem’s interpretation is inconsistent with the plain language, which refers to the year-long period preceding the “present[.]” RJN Ex. 1 at § 3.15.

As demonstrated above, all of Lorem’s alleged breaches are based on the false premise that the CE certificates for the UK facility were included in the APA, and fail to plausibly state a claim.

B. Lorem Fails to Allege that Plus Breached Any Implied APA Terms

Lorem’s implied covenant claim fails because it cannot identify any implied obligation of the APA that Plus breached. Lorem’s Opposition describes purported implied obligations “to prevent or rectify any discrepancy between what Plus promised to deliver and what was actually delivered.” Opp. at 10-11. There is no allegation in the Complaint identifying any such implied obligations, but in any event, this new theory of the implied obligations: (1) is inconsistent with

⁵ There is also no allegation that the March 2019 shipment violated any UK or EU law; it did not.

⁶ *See, e.g.*, Recall (n.), MERRIAM WEBSTER’S DICTIONARY; <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>.

the APA; (2) is contrary to the law; and (3) Lorem does not allege breach of any of them.

First, there can be no implied obligation for Plus to “prevent or rectify” any issues with the CE certificates for Cytori UK because Plus made no promise in the APA to deliver any such certificates. *See* Section II(A), *supra*. In Section 3.10(b), Plus promised to deliver a single CE certificate that was valid and in full force and effect. *See id.* But Plus did not attach any CE certificate for Cytori UK; it made no representation that such certificates would be conveyed to Lorem, or that they were valid and in full force and effect. And it disclosed that the UK facility was “not in compliance” and not audited. There is no discrepancy for Plus to prevent or rectify.

Lorem’s reliance on *Alltrista Plastics, LLC v. Rockline Indus., Inc.* is misplaced. *See* Opp. at 10 (citing 2013 WL 5210255, at *8 (Del. Sup. Ct. Sep. 4, 2013)). In *Alltrista*, the parties’ Supply Agreement had an explicit term requiring that they work together to agree on specifications, and that the supplied canisters materially conform. *Alltrista*, 2013 WL 5210255 at *8. The court found that agreement created an implied obligation to work together to determine why the canisters failed. *Id.* There is no provision in the APA requiring Lorem and Plus to “work together” relating to the validity of the CE certificates. To the contrary, the APA explicitly disclaimed any implied, continuing obligations between the parties after closing. RJN Ex. 1 at § 6.04.

Second, under the law, there can be no implied obligation concerning topics that the parties discussed in negotiations. *See* Mot. at 14-16. Lorem does not dispute that the parties discussed the Cytori UK facility’s lack of compliance and missing audits. Nor can it, because those circumstances are included in Disclosure Schedule 3.10(b). If Lorem wanted Plus to promise to “obtain full compliance” with the Cytori UK certificates, or work with it to cure any issues with validity of the certificates, those promises should have been expressly included in the APA. *Id.*

Third, Lorem’s claim fails because it does not allege any post-APA conduct that would breach its new implied obligations. Lorem argues now that Plus impliedly promised to obtain full

CE certificate compliance, cure any cancellations of the certificates, and work with Lorem to cure defects and restore their validity. Opp. at 11; *see also id.* at 2 (implied covenant claim “arises from [Plus’s] failure to take any steps to rectify the compliance issues post-APA”). But, unlike in *Alltrista*, there is no allegation that Plus refused any requests by Lorem to assist with curing any issues with the CE certification after the deal closed. *See* 2013 WL 5210255, at *8. Nor could there be, because Lorem did not contact Plus about the CE certificates for more than 18 months.

C. Lorem Fails to Allege Fraudulent Inducement

1. Lorem’s Fraudulent Inducement Claim Uses Improper Bootstrapping

Delaware courts routinely dismiss fraud claims that, like here, are repackaged breach of contract claims with the same damages allegations. *See Heritage Handoff Holdings, LLC v. Fontanella*, No. 1:16-CV-00691-RGA, 2019 WL 1056270, at *5 (D. Del. Mar. 6, 2019). Lorem seeks the same relief—\$6 million in compensatory damages—through its breach of contract and fraud claims, based on alleged misrepresentations about the CE certificates before and in the APA. *See* Compl. ¶¶44, 56, Prayer ¶ 1. Lorem’s comparison of its damages allegations for its breach of contract and fraud claims demonstrate that they are the same, with immaterial differences in wording.⁷ *See* Opp. at 16; *EZLinks Golf, LLC v. PCMS Datafit, Inc.*, 2017 WL 1312209, at *6-7 (Del. Super. Ct. Mar. 13, 2017) (dismissing fraud claim when damages “appear materially identical” to contract damages and the fraud claim “pleads neither for rescission nor rescissory damages”). Because Lorem’s fraud claim merely “rehashes” the damages caused by the alleged breach of the APA, it should be dismissed. *EZLinks Golf*, 2017 WL 1312209, at *7.

2. Lorem Fails to Allege Fraudulent Inducement With Particularity

Lorem fails to allege a false statement with particularity. *See* Mot. at 17-18. Vaguely referring to general statements made “throughout the negotiation process” is not sufficient to

⁷ *Anschutz* confirms a plaintiff can plead fraud and contract claims if it seeks a fraud remedy “based in rescission, or rescissory damages,” “not compensatory damages.” 2020 WL 3096744, at *15.

identify a misrepresentation.⁸ *See* Opp. at 13-14; *see also* Compl. ¶ 19(v). For example, Lorem does not allege the statement, when it occurred, or the date or location.⁹ And for the one alleged misstatement it identifies—the disclosure in Schedule 3.10(b) that the UK facility was not in compliance and behind on audits—Lorem does not argue that the statement itself was false. Lorem instead argues that it “created the false impression that the CE certificates actually existed and that the only action needed was to conduct an overdue audit.” Opp. at 18. There is nothing in the APA—which conveyed no rights to any CE certificates for the UK facility—supporting this “*impression*.” Lorem cannot plausibly allege it reasonably relied on unspecified verbal statements regarding the validity of CE certificates that were not even part of the APA.¹⁰ *See* Mot. at 19-20.

D. Lorem Fails to Allege Negligent Misrepresentation

The negligent misrepresentation claim should be dismissed because Lorem fails to allege a fiduciary or other special duty. Lorem does not dispute that the parties have no fiduciary relationship. *See* Opp. at 19-20. Negligent misrepresentation “is a viable claim in Delaware only when there is a fiduciary” or similar special relationship. *Keystone Assocs. LLC v. Barclays Bank PLC*, No. 19 796 (MN), 2020 WL 109008, at *4 (D. Del. Jan. 9, 2020); *see also* *Perlmutter v. Salton, Inc.*, No. 09-690-GMS, 2010 WL 3834040, at *5 (D. Del. Sept. 24, 2010), *aff’d* sub nom. *Perlmutter v. Russell Hobbs, Inc.*, 450 F. App’x 161 (3d Cir. 2011) (“[T]he existence of a

⁸ Lorem argues it need only “allege the circumstances of the fraud with detail sufficient to apprise the defendant of the basis for the claim.” Opp. at 12 (quoting *LVI Grp. Inv., LLC v. NCM Grp. Holdings, LLC*, 2017 WL 1174438, at *4 (Del. Ch. Mar. 29, 2017)). *LVI Group* explains these “circumstances” include “time, place, and contents of the false representations; the facts misrepresented; the identity of the person(s) making the misrepresentation; and what that person(s) gained from making the misrepresentation.” *LVI Group*, 2017 WL 1174438 at *4.

⁹ Lorem vaguely refers to unspecified “due diligence materials” that allegedly stated “suspensions or cancellations (NONE).” Opp. at 13. Lorem fails to allege any context about this isolated phrase that might indicate it was referring to the CE certificates for Cytori UK.

¹⁰ Lorem’s argument that there is no “contradiction” between (1) its supposed belief it purchased valid CE certificates, and (2) the APA that did not include those CE certificates and that disclosed the non-compliance of the UK facility is nonsensical; they cannot both be true. *See* Opp. at 3-10.

fiduciary duty does not arise merely by entering into an agreement.”); *Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 144 (Del. Ch. 2009) (negligent, or equitable, fraud is not available absent “special equities, typically the existence of some form of fiduciary relationship”). That type of special relationship does not exist between parties to arms’ length negotiations.¹¹ *Airborne Health*, 984 A.2d at 144; *Prairie Cap., III, L.P. v. Double E Holding Corp.*, 132 A.3d 35, 52 (Del. Ch. 2015) (“In an arms’ length contractual setting like the negotiation of the SPA, a party has no affirmative duty to speak.”). This claim further fails because it cannot be based on a duty to provide information arising from a contract, as Lorem argues. *See Columbus Life Ins. Co. v. Wilmington Tr. Co.*, No. 20-735 (MN), 2021 WL 3886370, at *7 (D. Del. Aug. 31, 2021).

Finally, the claim should be dismissed because Lorem has not alleged that Plus provided it false or misleading information about the status of the UK CE certificates, for the reasons explained above and in the Motion to Dismiss.¹² *See* Section II(C), *supra*; Mot. at 16-17, 20.

III. CONCLUSION

For the foregoing reasons, Plus respectfully requests that the Court dismiss the Complaint with prejudice. Any amendment cannot change the terms of the APA, and would thus be futile. *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 465 (3d Cir. 2021).

¹¹ Lorem cites inapposite cases for its position that no fiduciary or special duty is required, as long as it alleges a partial statement or omission of facts basic to a transaction. *See* Opp. at 19. It cites *Mentis v. Del. Am. Life Ins. Co.*, which addresses duty to speak in the context of fraud, not negligent misrepresentation. *See* 1999 WL 744430 (Del. Super. July 28, 1999). It cites *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, which is also not a negligent misrepresentation case, to argue its license with Plus created a relationship of trust. *See* 901 A.2d 106, 113 (Del. 2006). The *Wal-Mart* language that Lorem selectively quotes merely defines a fiduciary relationship. *Id.* Finally, it cites *In re Student Fin. Corp.*, which discusses the Restatement of Torts in the context of fraud and negligent misrepresentation claims. *See* 2004 WL 609329, at *5 (D. Del. Mar. 23, 2004). The cases upon which the court relies all involve fraud, not negligent misrepresentation. *Id.* To the extent *In re Student Fin. Corp.* can be read to hold that negligent misrepresentation does not require a fiduciary or special duty, this Court should decline to follow it.

¹² Lorem again ignores its heightened pleading requirements under Rule 9. *See* Mot. at 20.

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